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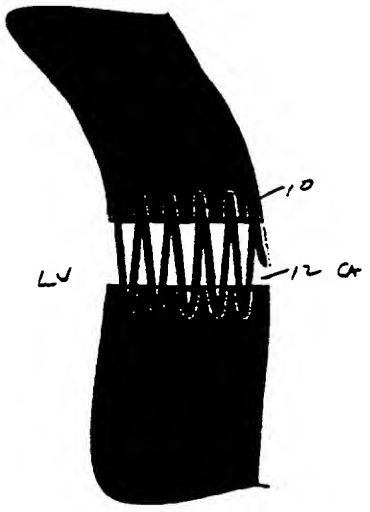
(54) Title: CORKSCREW REINFORCED LEFT VENTRICLE TO CORONARY ARTERY CHANNEL

Corkscrew Reinforced LV – CA Channel



Ablated Channel

(57) Abstract: A coil is screwed into the heart wall HW b[redacted]e left ventricle and coronary artery, followed by forming of a channel with laser, plasma, electrical, or mechanical device th[redacted]gh.

CORKSCREW REINFORCED LEFT VENTRICLE TO CORONARY ARTERY CHANNEL

Background of the Invention

Field of the Invention

This invention relates to method and apparatus for forming a channel to allow communication of fluids from one portion of a patient's body to another. and more particularly, to a device that can communicate blood between the left ventricle and coronary arteries or veins.

Description of the Related Art

Currently there exists a shunting concept that establishes a passage from the left ventricle directly to the coronary artery by the placement of a stent or hollow tube in a channel formed therethrough. Other designs also suggested that it might be possible to have a stent-less channel (see U.S. Patent No. 5,662,124). Both designs have to deal with problems arising from the contraction and multidimensional movements of the heart wall in relation to the device. For a straight hollow tube the movement may create irritation between the tissue and the metal interface that may lead to a chronic inflammatory response. and maybe even to dislodgement of the tube. For a collapsible or expandable "wire" stent the constant movement can lead to fracture from cyclic fatigue (this has been documented in vivo humans - by Stent Medtronic). With respect to blood compatibility a solid tube presents maximum foreign surface to the blood of materials that are all relatively thrombogenic. While a wire or open stent design has less surface area exposed to blood. the profile of the stent in the flow field is less optimal and requires optimal placement.

Summary of the Invention

What is primarily needed is a device that can control the shape of the open channel between the left ventricle and coronary artery, and can withstand long and continuous complex movement without causing irritation. dislodgement. or fracture. An alternative approach to spikes. and stents. is the use of a screw in coil. The design of such a coil would be much like that of a corkscrew. This same design has been used on implantable pacemaker leads for years to anchor the electrode tips into the endocardium of the heart. This design yields very high stability in terms of pull out force and survival against mechanical

dislodgement. It is also well tolerated without chronic inflammatory responses. Another advantage is in placement of the device, as it can be removed with ease and without significant tissue trauma should the initial placement attempt be less than optimal.

Brief Description of the Drawings

FIGURE 1 illustrates a partial cross-sectional view of a coil screwed into the heart wall between the left ventricle and coronary artery.

FIGURE 2 illustrates a partial cross-sectional view of a channel formed through the coil of **FIGURE 1**.

Detailed Description of the Preferred Embodiment

FIGURES 1 and **2** roughly show the preferred design, which would comprise first screwing in a coil 10 into the heart wall HW between the left ventricle LV and coronary artery CA (**FIGURE 1**), and then followed by forming of a channel 12 by, for example, laser, plasma, electrical, or mechanical device (**FIGURE 2**). At this time it would be preferred to use the plasma ablation technique as the diameter of the channel can be controlled with considerable accuracy at the dimensions one would want, and also the asymmetry can be controlled.

In one embodiment, the corkscrew or coil 10 may be configured to have a desired pitch and spacing so that insertion of the coil 10 into the heart wall does not puncture through the coronary artery CA. This is accomplished by choosing an entry point for the coil 10 adjacent the coronary artery, and screwing the coil 10 into the heart wall such that the coronary artery is positioned in between the turns of the coil as the coil is inserted. In this embodiment, the spacing between the turns of the coil is greater than the diameter of the coronary artery.

Up until now it has been suggested that blood exposure to non endothelialized tissue surfaces would be a problem for a formed, stentless channel. In reality the challenge of the denatured proteins on the surface of a formed channel is certainly no more than that of a metal surface of a tube or stent concept.

It is further envisioned that the channel formed would be optimal for "paving" with a biocompatible polymer such as a PEG macromer (Focal of MA), and this could be a rapid and catheter-based method of in situ modification of the channel to improve blood compatibility.

It is also conceivable that the "corkscrew" can be placed on the distal tip of a catheter

and also serves as a guide for the subsequent forming device to make the channel. Electrical circuits can be designed to operate within defined distances from the corkscrew, and can control the forming device that requires energy sources.

An additional advantage of the corkscrew is that a slight projection into the ventricle would not create dead spots for blood pooling like that of a hollow tube. It also would not be subject to rapid over insertion as is the case with puncture like devices.

Finally the corkscrew is not actually inside the channel and therefore presents no problems of profile and placement, as would be the case with an expanding stent design. The latter variable has been thought to be the most critical parameter in intravascular stent use.

It will be appreciated that although the above embodiments have been described as being used between the coronary artery and left ventricle, the methods and apparatus described above can be used between any heart chamber and blood vessel, or through any other body tissue between two body lumens in which a channel of blood is desired to be formed.

The embodiments illustrated and described above are provided merely as examples of certain preferred embodiments of the present invention. Various changes and modifications can be made from the embodiments presented herein by those skilled in the art without departure from the spirit and scope of the invention, as defined by the appended claims.

WHAT IS CLAIMED IS:

1. A method for forming a channel between a first body lumen and a second body lumen through body tissue, comprising:

screwing a coil into the body tissue between the first and second body lumens; and

forming a channel through the coil.

2. The method of Claim 1, wherein the channel is formed using a device selected from the group consisting of a laser, plasma, an electrical device and a mechanical device.

3. The method of Claim 1, wherein the first body lumen is a heart chamber, the second body lumen is a coronary artery or vein, and the body tissue is a heart wall.

4. A reinforced channel between a heart chamber and a blood vessel, comprising:

a coil extending through the heart wall between the heart chamber and blood vessel; and

a channel through the coil.

5. The reinforced channel of Claim 4, wherein the channel through the coil is formed by ablation.

6. The reinforced channel of Claim 4, wherein the coil does not contact the channel.

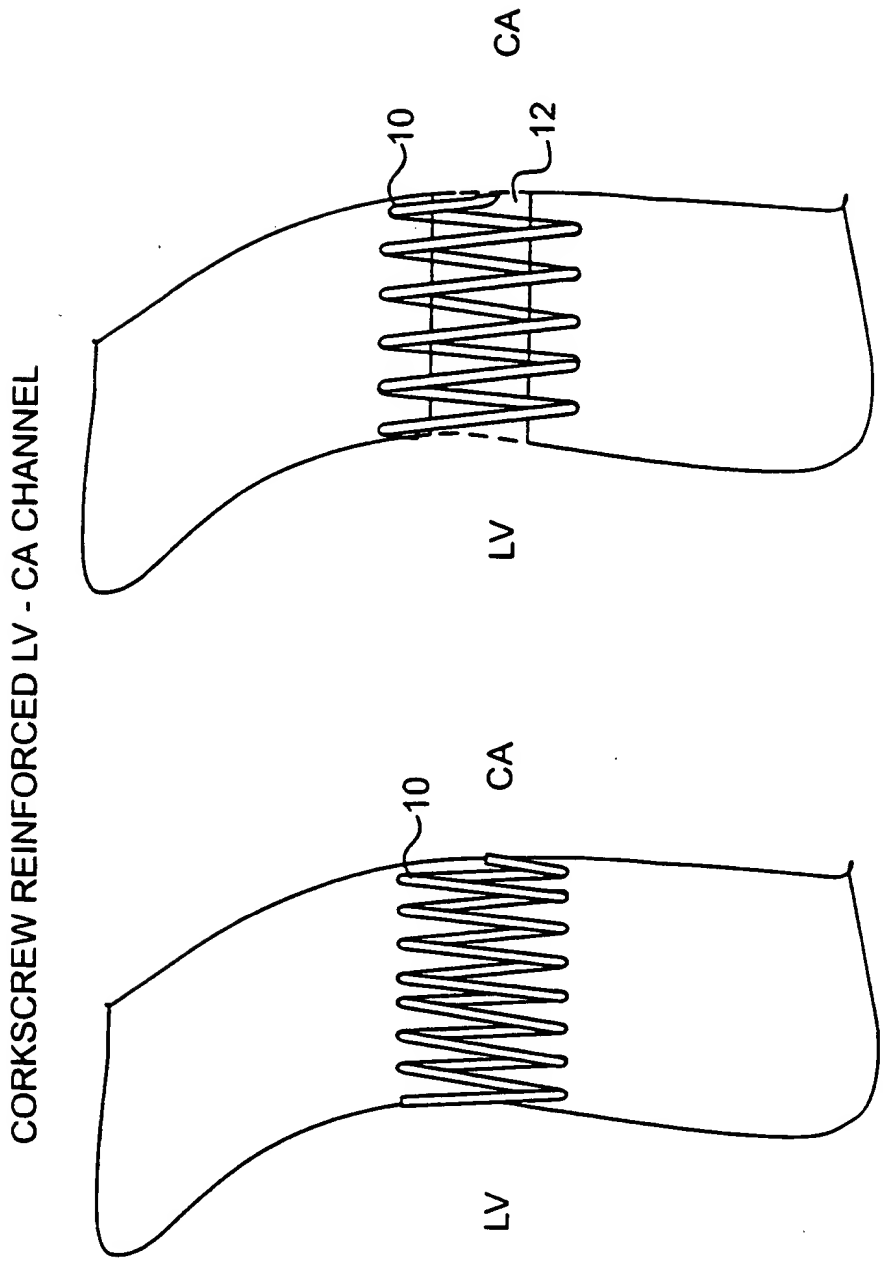

CORKSCREW REINFORCED LV - CA CHANNEL
10
CA
LV
CORKSCREW CENTERED
10
12
CA
LV
ABLATED CHANNEL

FIG. 1

FIG. 2

INTERNATIONAL SEARCH REPORT

Inti donal Application No
PCT/US 00/21120

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 878 751 A (HUSSEIN H) 9 March 1999 (1999-03-09) the whole document	4-6

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inf ional Application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication da.e
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